



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

TB Notes
Vol. 4, 1996

Dear Colleague:

We come to the end of another year of changes and accomplishments. This is a good time to review and reflect upon some of the events that have transpired.

At the risk of being redundant, I want to reiterate the significance of our recent TB control accomplishments. As you know, TB cases in the US declined 6% last year, from 24,361 new cases in 1994 to 22,812 new cases in 1995. This means we have nearly brought the annual number of new cases back down to the 1985 all-time low of 22,201; we have already reached the lowest case rate ever with this year's rate of 8.7/100,000. Yet the problems and challenges that caused TB to resurge between 1985 and 1992—HIV, transmission in congregate settings, poverty and homelessness, immigration from areas where TB is common—are still here and still capable of causing another resurgence of TB. It is therefore imperative that we stay the course as we seek innovative ways to improve our efficiency.

The year 1996 brought changes and new challenges. Our center, formerly the National Center for Prevention Services (NCPS), was reorganized and renamed the National Center for HIV, STD, and TB Prevention, with Helene Gayle, MD, MPH, appointed director. A new Program Coordination Unit (PCU) was established as a pilot program to test the feasibility of using multiprogram consultants (HIV, STD, and TB) as the contacts for state officials in all three program areas. Dixie E. Snider, MD, MPH, my predecessor as the director of DTBE, was appointed Associate Director for Science for CDC. Alan Hinman, MD, former director of NCPS, retired from CDC this past summer and since August 1 has been employed as senior consultant for public health programs with the Task Force for Child Survival and Development. The annual TB Controllers' workshop had to be rescheduled from January to September because the furlough of federal employees caused delays in the workshop planning process; I believe having the conference in September worked out well and would like to maintain this schedule for future workshops. Managed care has emerged as a major concern to public health agencies. The 22nd USPHS trial for TB therapy, also known as the Rifapentine Clinical Trial, was started; this is the first PHS clinical trial of a new TB drug to be conducted in 25 years! And cooperative agreement funds were awarded in record time this year owing to the hard work of the grantees and the program consultants.

The Tuberculosis Information Management System (TIMS) has been under development for several years now, and in 1997 we will be seeing the result of our collective efforts. At this time we anticipate implementation in the summer of 1997. The development of TIMS has been a joint effort between CDC headquarters and

health department staff. This was done to ensure that the system would be useful to the persons who will actually work with it. We recently held the TIMS prerelease training courses in Atlanta and benefitted from the feedback provided by 168 future users of TIMS. The two software systems that are currently in use, SURVS-TB for surveillance and TBDS for patient management and program evaluation, will be phased out in 1997 and the data in the two systems converted to TIMS.

Dr. Chris Braden of the Surveillance and Epidemiology Branch (SEB), DTBE, made a presentation at the National TB Controllers' Workshop in September on the Tuberculosis Genotyping and Surveillance Network, which consists of seven regional research laboratories and seven sentinel sites funded to study *M. tuberculosis* DNA fingerprinting methods. We have an article in this issue from Dr. Braden on DNA fingerprinting methods, their epidemiologic uses and interpretations, and their application to TB control.

The staff of SEB, in collaboration with the National TB Controllers Association (NTCA), have developed new recommendations for counting reported TB cases. These recommendations will be published and disseminated early in 1997. In the interest of providing this information as soon as possible to the persons who need it, we have attached a draft copy of the recommendations at the end of this issue of *TB Notes*.

Don't forget to register your location, or determine the broadcast viewing site closest to you, for the broadcast of *TB 2000: Fundamentals of Clinical TB and TB Control*. This is a live, interactive, three-part satellite training course for medical professionals and is a joint project of the Francis J. Curry National TB Center of San Francisco, the Charles P. Felton National TB Center at Harlem Hospital, and the New Jersey Medical School National TB Center. The date of the broadcast of the first part is January 23, 1997. Please see *TB Notes*, Vol. 3, 1996, as well as the "Calendar of Events" section of this issue, for more information on this event.

I extend my heartfelt thanks to everyone involved in the fight against TB for all your hard work and my best wishes for a happy, safe, and healthy holiday season.

Kenneth G. Castro, MD

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NOTE: The use of trade names in this issue is for identification only and does not imply endorsement by the Public Health Service or the U.S. Department of Health and Human Services.

—Reported by Gary Simpson, MD, MPH, PhD,
and Doris Fields, MA
New Mexico TB Control Program

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contact Ann Lanner, *TB Notes* Editor
CDC/NCHSTP/DTBE, Mail Stop E10

1600 Clifton Road, NE
Atlanta, Georgia 30333
Fax: (404) 639-8960

DIRECTOR, DTBE
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California Training Program for Local Health Jurisdictions

The Francis J. Curry National TB Center (CNTC) is implementing a statewide TB training program to provide on-site, targeted training to local health jurisdictions within California. The purposes of

this training effort are to enhance local TB control and prevention programs and to build local capacity to meet regional training needs. The California Training Program is a partnership among local health jurisdictions, the California Department of Health Services Tuberculosis Control Branch, and CNTC.

The process to implement this training program in a health jurisdiction includes

- Needs assessment activities to identify TB control program elements that could be enhanced with additional training
- Identification of responsibilities of both the CNTC and the local health jurisdiction that are then outlined in a training agreement document
- Implementation of one or more training courses for TB control program staff and/or health care providers in the community
- Evaluation efforts to assess the impact of the training interventions

In addition, CNTC and the state TB Control Branch will work with the local health jurisdiction to develop a follow-up plan for other program improvements that are identified in the needs assessment process or during the training(s).

The San Joaquin County Public Health Services is the first California health jurisdiction to participate in this training program. CNTC also plans to provide targeted, on-site training to staff of the California Department of Corrections who have TB program responsibilities in several prisons in the southern California region.

The California Training Program is funded for 2 years by the California Department of Health Services, TB Control Branch. The role of the TB Control Branch may include participating in needs assessment activities including interpretation of

surveillance and program performance data, serving as training faculty, participating in post-course evaluations, and giving technical assistance.

If you are interested in finding out more about this program, please contact Mona Bernstein, Statewide Training Program Coordinator, at (415) 502-4600, or send an e-mail to mona@nationaltbcenter.edu.

—Reported by Mona Bernstein
Francis J. Curry National TB Center

Four Corners TB Control Collaboration

The New Mexico (NM) TB Program Staff actively participated in the planning process for the second annual Four Corners TB Control Conference in Farmington, NM, on October 22-23, 1996. Department of Health staff from Colorado, Utah, Arizona, and NM joined the Navajo Nation and the Indian Health Service for reports of TB activities that addressed common problems. Mack Anders of DTBE attended and participated in this meeting, sharing data and strategic ideas from a national perspective. The topics included "A Regional TB Register," "A Regional TB Control Directory," "Electronic Data Exchange and Access Issues," "A Mobile TB Care Plan," "The Role of Managed Care in TB Control," and "Respecting Other's Jurisdictional Boundaries." A large population of Native Americans live in this four-state area and cross borders regularly for care. The NM counties in the four corners area include Cibola, McKinley, and San Juan.

Collaboration among the four states, the Indian Health Service, and the Navajo tribe is critical to addressing unique issues of TB among Indians in NM. Participants in this conference generated programmatic activities that we expect to lead to

successful contact investigations, tracking, treatment, and follow-up. In addition to focusing on problems that are common to all parties, NM participated in a strategic session with Navajo Nation and Indian Health Service staff around contact tracing and treatment follow-up on a specific case.

—Reported by Doris Fields, MA
and Jeanne Smithpeter, RN, BSN, MSN
New Mexico TB Control Program

The Drug Pricing Program

The Office of Drug Pricing Program (ODPP) was created in November 1992 to implement Section 602 of the Veterans Health Care Act of 1992. This Act mandates that drug manufacturers participating in Medicaid must sign an agreement with the Department of Health and Human Services to provide **discounted outpatient pharmaceuticals** to certain federal grantees. TB grantees (i.e., recipients of CDC TB cooperative agreement funds) are included in this law in the following excerpt:

"(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) of this title (relating to treatment of TB) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7)."

In order for a TB clinic to participate in the Drug Pricing Program, it must meet certain criteria. First, the state must provide CDC with a yearly certification of eligibility. Second, the clinic must notify ODPP of its Medicaid billing status. Specifically, the clinic must inform ODPP whether or not it bills Medicaid for pharmaceuticals. If the clinic does bill Medicaid, it must specify if services are billed under a separate Medicaid number or if

pharmaceuticals and services are billed under the same Medicaid number. Additionally, it is the clinic's or entity's responsibility to ensure that the discounted pharmaceuticals are used in **participating clinics and only dispensed to patients of these clinics.** The clinic or entity must develop a tracking system to prevent diversion of discounted drugs to entities and patients not eligible to receive them.

Clinics have reported substantial savings on their pharmaceutical purchases utilizing the Drug Pricing Program. The key challenges are understanding the program and then, if applicable, participating in it.

A common area of confusion is the issue of who is eligible to receive these discounted drugs. These issues are addressed in *Federal Register* Notice #94-11643, published May 12, 1994, titled "Entity Guidelines."

If you would like more information or have questions about the program, please call the Office of Drug Pricing at (301) 594-4353.

—Reported by Mary Jackson
Health Resources and Services Administration

***M. tuberculosis* DNA Fingerprinting**

DNA fingerprinting, also called restriction fragment length polymorphism (RFLP), is used to identify related strains of *M. tuberculosis*. This ability to accurately identify related strains of *M. tuberculosis* can help define the people and places involved in *M. tuberculosis* transmission. TB control personnel can use this information to design and implement more effective TB control measures. However, the interpretation of *M. tuberculosis* DNA fingerprint patterns can be difficult; it may change according to the method

used for DNA fingerprinting, the definitions used to compare fingerprint patterns, and the characteristics of the patient population.

Basis of *M. tuberculosis* DNA fingerprinting.

Currently, most *M. tuberculosis* DNA fingerprinting is based on a small piece of repeating DNA, named IS6110, that may be present from 1 to 20 or more times in the *M. tuberculosis* genome (see Figure 1).

The genome is split by an enzyme at many specific sites, including one within IS6110. Because the number and position of IS6110 vary among strains, the splitting produces DNA fragments of different sizes (reflected in the name restriction fragment length polymorphism, or RFLP). These DNA fragments contain small electrical charges that cause them to separate by electrical current in an agarose gel, with the smaller fragments traveling further through the gel. The separated DNA fragments are then transferred onto a nylon membrane. The fragments from the isolate containing IS6110 are bound to a matching piece of IS6110 DNA labeled with a radioactive or light-producing molecule on the membrane; this makes the isolate fragments visible. The membrane is exposed to x-ray film, producing banding (fingerprint) patterns on the film. Unrelated strains will differ in numbers and positions of IS6110 in their genome and in DNA fingerprint patterns.

Figure 2 is an example of a film showing several DNA fingerprint patterns. Each lane represents an isolate from a different patient with TB except lanes 1, 10, and 20, which are DNA standards used to estimate the size of the DNA fragments. Each band in these lanes represents one copy of IS6110 in the genome of the isolate.

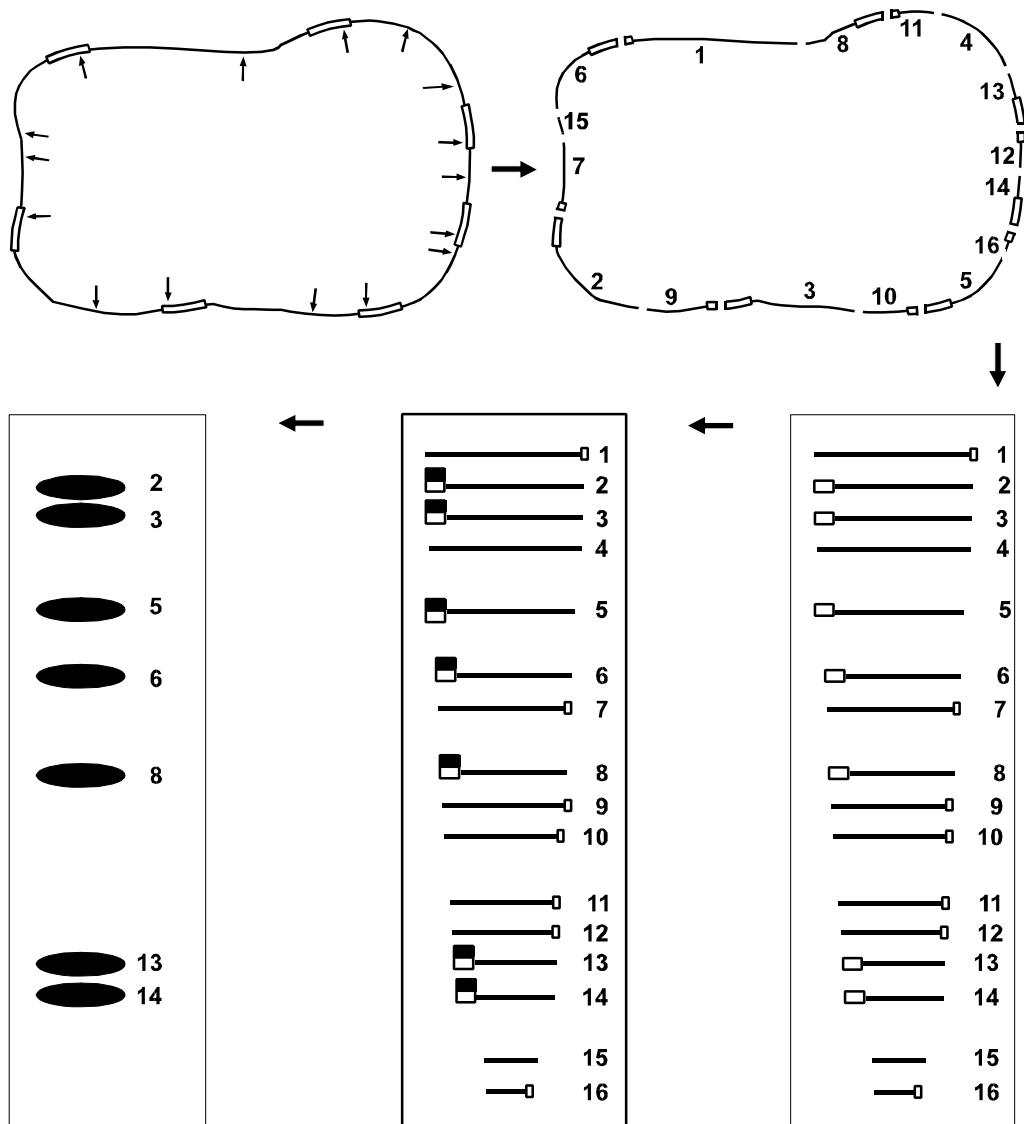


Figure 1. Basis for *M. tuberculosis* DNA fingerprinting

- M. tuberculosis* genomic DNA includes conserved, repeating elements (open boxes). The DNA is cleaved at sites specific for an endonuclease enzyme (arrows), including at a site within a genetic element.
- Varying size DNA fragments are produced (numbered here according to size). Some fragments contain a portion of the genetic element.
- The DNA is separated by agarose gel electrophoresis according to the size of the fragments, the largest size fragments traveling the least distance through the gel.
- The fragments are transferred to a nylon membrane. A DNA probe matching one side of the genetic element and labeled with a light or radiation-emitting molecule is applied (black boxes).
- X-ray film is exposed to the nylon membrane, the light or radiation from the probe producing a banding pattern on the developed film. The number and position of bands corresponds to the original number and position of the genetic element in the genome.

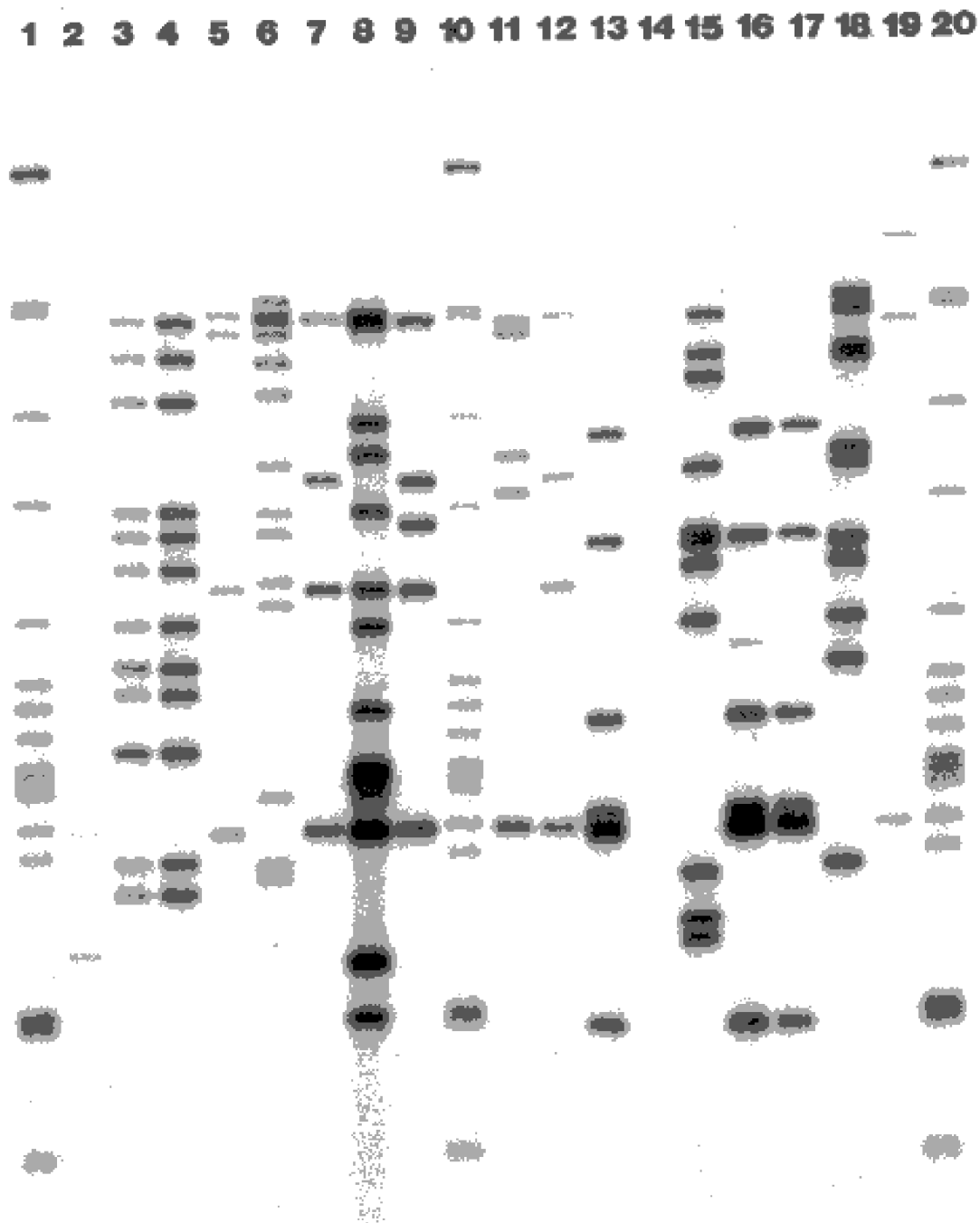


Figure 2. DNA fingerprints of *M. tuberculosis* isolates from different patients

- a. Lanes 1, 10, and 20 contain standardized DNA-producing fragments of known molecular weights. The molecular weights of other fragments are computed using these standards.
- b. Lane 14 contains no DNA.
- c. Patterns in Lanes 3 and 4 match exactly.
- d. Patterns in Lanes 16 and 17 match with the exception of an extra band in Lane 16.

Notice that some strains contain few copies of IS6110, as in lane 19 with 3 bands, and some strains have many copies of IS6110, as in lanes 3 and 4. The patterns in lanes 3 and 4 also match one another, which would indicate that these two isolates are probably closely related. Note that the patterns in lanes 16 and 17 are identical with the exception of one band. The interpretation of patterns such as these is controversial. Some researchers will accept a difference of one band and say these represent the same strain; others may disagree.

Current Uses of *M. tuberculosis* DNA Fingerprinting in TB Epidemiology

The investigations in the early 1990s of the nosocomial and institutional transmission of TB, including multidrug-resistant TB, introduced *M. tuberculosis* DNA fingerprinting as a valuable

epidemiologic tool [1-4]. Since then, *M. tuberculosis* DNA fingerprinting has had numerous applications, the most frequent being outbreak investigations, the identification of laboratory cross-contamination of *M. tuberculosis* cultures, and the study of TB transmission in large populations.

Epidemiologists have used DNA fingerprinting of *M. tuberculosis* isolates from patients involved in outbreaks to clarify chains of TB transmission and potentially to redirect investigations. One investigation involved TB transmission in a renal transplant unit [1]. The diagrams in Figure 3 show how this investigation changed with the addition of DNA fingerprint information. Each dot represents a patient on the renal transplant ward who was later diagnosed with TB. A theoretical chain of transmission among the 11

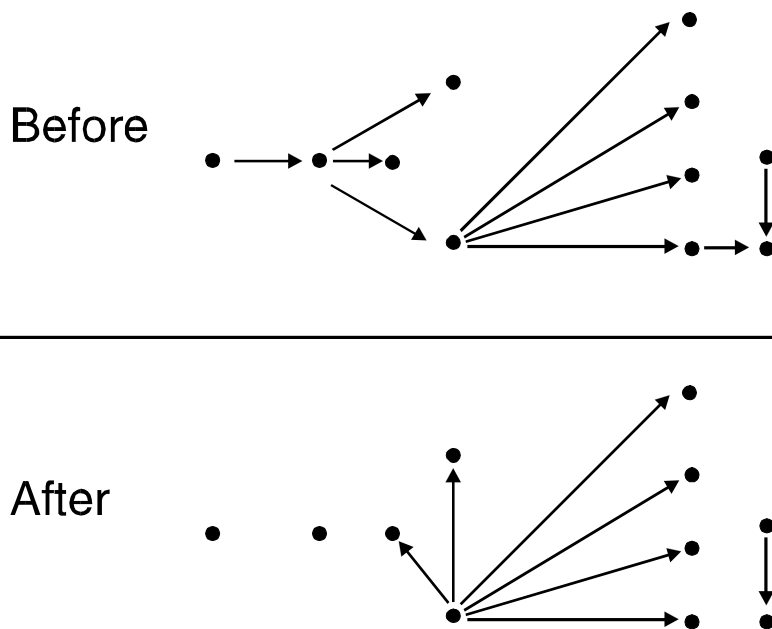


Figure 3. Potential chains of TB transmission before and after DNA fingerprinting of isolates. Epidemiologic investigation of 11 TB patients hospitalized on one ward identified a potential chain of transmission among all patients involving five generations of spread. Results of DNA fingerprinting identified four different strains; one common to 7 patients and another common to two patients, each involving just one generation of spread. In addition, the DNA fingerprint pattern of a separate patient in another hospital (not shown) matched that of the seven patients sharing the common strain above. Investigations around this patient identified her as the source case in this outbreak and responsible for *M. tuberculosis* infection in 19 health care workers.

patients based on the history of exposures in the hospital prior to DNA fingerprinting included four generations of spread involving all 11 patients. However, DNA fingerprinting of patient isolates showed that the first two patients had isolates with unique DNA fingerprints and were not involved in the outbreak. An additional two patients were infected by a different strain. For the remaining seven, one apparently infected the others at a time when all were hospitalized on the transplant ward at the same time. In this outbreak, DNA fingerprinting was very helpful in defining the extent of transmission and the patients involved.

DNA fingerprinting has also been used to help detect laboratory cross-contamination of *M. tuberculosis* cultures [5-8]. Two reports now identify this as a relatively common phenomenon, possibly responsible for 2% to 5% of all positive cultures [6, 8]. Occasionally laboratory cross-contamination has been responsible for a large number of positive *M. tuberculosis* cultures in clinical laboratories [9]. Evidence that an *M. tuberculosis* culture-positive specimen is the result of laboratory cross-contamination includes the following: (1) the patient providing the specimen had no observed acid-fast bacilli in any smears and only one specimen was positive for *M. tuberculosis*, (2) the clinical course of the patient was inconsistent with TB, (3) a culture-positive specimen from another patient was processed in the laboratory the same day as the suspected specimen, (4) this putative source isolate has the same DNA fingerprint, and (5) there were no known epidemiologic connections between the patient who produced the putative source specimen for cross-contamination and the patient with the potentially false-positive culture [6].

There are several important consequences to

recognizing laboratory cross-contamination of *M. tuberculosis* cultures. First, once cross-contamination has been recognized, a thorough review of laboratory procedures in facilities involved may identify the mode of bacterial transfer between cultures [5]. Procedures can then be modified to prevent continued cross-contamination. In addition, patients misdiagnosed with TB based on false-positive culture results can have their diagnosis corrected and any unnecessary tests and therapy discontinued. TB prevention and control programs can avoid unnecessary investigations of sources and contacts, can save the cost of incentives to aid in patient adherence to treatment and the cost of directly observed therapy, and can reduce or eliminate the use of unnecessary drugs. Finally, patients erroneously diagnosed with TB can be removed from local and national TB surveillance systems.

M. tuberculosis DNA fingerprinting has also been applied to the investigation of TB transmission in large populations [8, 10-13]. In two of the earliest studies conducted in the United States, one in San Francisco [8] and one in New York City [11], the authors assumed that isolates with matching DNA fingerprints were epidemiologically related and represented recent transmission of *M. tuberculosis* among the patients involved (i.e., within the 2 years prior to diagnosis). In these studies, 30% to 40% of patients had isolates with DNA fingerprint patterns that matched at least one other isolate; therefore the authors concluded that in these groups up to 40% of TB cases were due to recent transmission, much greater than the previously accepted proportion of approximately 10% [14]. This conclusion implies that current TB control practices may not be maximally effective in decreasing TB transmission. However, the study populations were urban residents, a large proportion of whom

were HIV infected. The epidemiology of TB transmission in such populations may not be generalizable to other populations in the United States. This was shown in a study conducted in the state of Arkansas [13], where the population is largely stable and rural with a relatively low rate of HIV infection. In this circumstance, matching *M. tuberculosis* DNA fingerprints were found in patients who had been infected with TB earlier in life and who had no epidemiologic connection to each other.

Population-based studies have also confirmed that strains cannot be reliably differentiated when IS6110 DNA fingerprint patterns have few bands [12, 13] or differ by one or two bands [15]. In the Arkansas study [13], significantly fewer epidemiologic connections were identified among patients whose isolates had five or fewer IS6110 copies compared to patients whose isolates had greater than five IS6110 copies (13% vs. 43%).

Researchers are finding that the methods are complex for the DNA fingerprinting of isolates from large populations and for the epidemiologic interpretations of the results. Both the particular methods used for DNA fingerprinting and the characteristics of the population studied need to be considered. Future population-based research concerning the transmission of *M. tuberculosis* using DNA fingerprinting needs to include a thorough epidemiologic evaluation of the social connections among the patients, so that we can determine the best DNA fingerprinting methods to apply and the most accurate conclusions to make.

M. tuberculosis DNA fingerprinting in the future

Much remains to be learned about *M. tuberculosis* DNA fingerprinting. New methods of DNA fingerprinting are being developed; some

are more rapid, such as those using PCR technology, and some may have a better ability to differentiate strains. Further research is required to better understand the relationship among DNA fingerprint patterns, genetic relatedness, and the epidemiologic relatedness of isolates. Only with better understanding of these relationships can *M. tuberculosis* DNA fingerprinting technology be appropriately applied and interpreted. Intensive research will continue in the use of *M.*

tuberculosis DNA fingerprinting in epidemiologic studies and in TB control. With this technology, TB controllers may be better able to identify specific populations and places in which TB transmission occurs, allowing more targeted, efficient, and effective interventions.

In both the European Union (formerly known as the European Common Market) and the United States, networks of DNA fingerprinting laboratories are being established. These laboratories will use standardized methods for DNA fingerprinting in order to share and pool results. In the United States, the network will also include seven sentinel surveillance sites—in Arkansas, California, Maryland, Massachusetts, Michigan, New Jersey, and Texas—that encompass varying TB patient populations. Staff of these sites will attempt to include isolates from all culture-positive TB patients within their areas. Demographic, clinical, bacteriologic, and risk factor information will be obtained for each patient. In addition, information concerning potential sources of infection or contacts with TB will be collected. The epidemiologic information and the DNA fingerprint analyses will be available for use in local TB control and incorporated into a central database at CDC for analysis at a national level. The network of TB DNA fingerprinting laboratories and sentinel surveillance sites will allow the more rapid and systematic study of

M. tuberculosis DNA fingerprinting and its application to TB control.

—Reported by Chris R. Braden, MD
Division of TB Elimination

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NURSING ISSUES

Update on the National TB Nurse Consultant Coalition

The National TB Nurse Consultant Coalition

(NTNCC) was organized in January 1995. It is a section of the National TB Controllers Association (NTCA). Active membership is designated for TB Controllers, and associate membership is for all nurses who do not function as TB Controllers for their city/county or state.

The purpose of NTNCC is to advance the elimination of TB in the United States and its territories. The mission of NTNCC is to advise and support the TB control officials of state, local, and territorial governments by providing a coordinated nursing perspective on issues vital to the success of TB prevention and control programs within NTCA. The NTCA/NTNCC offices are headquartered in Atlanta, Georgia. Walter Page is the Executive Director of NTCA and can be reached at 1 (888) 455-0801 for membership applications.

The 1996 annual NTNCC meeting was held on September 7, 1996, in Atlanta, Georgia. The afternoon session included a business meeting; the discussion and adoption of the TB Nursing Standards of Practice; an open forum for the discussion of TB nursing issues; and an educational session provided by Janice Boutoutte, RN, MS, CS, on the supervision and delegation to nonlicensed personnel. This was an exceptional meeting that gave nurses an opportunity to voice their concerns about TB issues and provided NTNCC information for future activities. The significance of this meeting was the adoption of the TB Nursing Standards of Practice based on the Standards of Clinical Nursing Practice of the American Nurses Association (ANA). A copy of the NTNCC Standards can be obtained from the NTCA office.

One of the activities that NTNCC will be pursuing during the next 12 months is ANA recognition of TB nursing as a specialty. Anyone wishing to

serve on the committee for this project should contact Walter Page.

It has been enlightening and heartwarming to see nurses gather together to share their common body of knowledge, and to demonstrate their concern for patients and for the elimination of TB. You, too, can be a part of history and make things happen. Please consider joining us now.

The next NTNCC meeting is scheduled to be held in San Francisco on Saturday, May 17, 1997, in conjunction with the American Thoracic Society TB Nurses Special Interest Group. Mark your calendars now!

Officers of NTNCC for 1996:

Helen Gretz, RN, MPH—President
Janice Boutoutte, RN, MS, CS—President-Elect
Gayle Gutierrez, RN, BS—Secretary-Treasurer

Officers for 1997:

Janice Boutoutte, RN, MS, CS—President
Evelyn Lancaster, RN, BSN, NE—President-Elect
Chris Fox, RN, BSN—Secretary-Treasurer
Brenda Ashkar, RN, MSN, PHN—Past President/Consultant

*—Reported by Helen Gretz, RN, MPH
National TB Nurse Consultant Coalition*

RESEARCH UPDATE

Update on USPHS Study 22, the Rifapentine Clinical Trial

The twenty-second U.S. Public Health Service TB therapy trial, also known as the Rifapentine Clinical Trial, began enrollment in April 1995. This controlled clinical trial is a randomized, non-blinded comparison of the efficacy and safety of two treatment regimens—twice-weekly isoniazid

(INH) and rifampin versus once-weekly INH and Rifapentine—in the continuation phase of therapy for pulmonary TB. The study is being conducted at 29 clinical sites and subsites across the United States and Canada; several subsites have been added this year by original parent sites. Study sites are located in Atlanta, Baltimore, Charlotte, Chicago, Denver, Durham, Ft. Worth, Houston, Little Rock, Los Angeles, Miami, Nashville, Newark, New York City, Phoenix, San Antonio, San Diego, San Francisco, Washington, DC, and Winnipeg, Canada. The projected total number of persons that will be enrolled is about 1,100. As of October 30, 1996, there were 570 subjects enrolled, of whom 61 (11%) were HIV positive. The enrolled subjects are 77% male, 17% non-Hispanic white, 40% non-Hispanic black, 24% Hispanic, and 13% Asian. Their mean age is 44 ± 14 years; 34% are foreign-born persons (excluding Canadians); 20% are homeless; 41% are alcohol users; and 16% are diabetics. Fifty percent have less than a high school education. Completion of enrollment is anticipated in late 1997. The trial's Data and Safety Monitoring Board met for the first time in October 1996 to review data on study progress and safety, and has recommended continuation of the trial. If you have questions about the clinical trial, or are interested in learning more about enrolling patients in the trial, please call the Research and Evaluation Branch, DTBE, (404) 639-8123.

—Reported by Andrew Vernon, MD, MHS
Division of TB Elimination

Clinical Trial to Compare the Specificity of Tuberculin Skin Test Antigens

The tuberculin skin test is the standard method used to diagnose infection with *M. tuberculosis*. The skin test involves intracutaneous injection of 5 tuberculin units (TU) of purified protein derivative (PPD) by the Mantoux technique.

Although newer procedures have been developed for the detection of *M. tuberculosis*, at present these techniques have limited clinical utility, and the tuberculin skin test remains the only readily available and widely used method for detecting latent infection with *M. tuberculosis*.

The objective of this clinical trial is to determine if the two tuberculin skin test antigens which are commercially available in the United States (Aplisol[®], produced by Parke-Davis, and Tubersol[®], produced by Connaught Laboratories, LTD) produce similar results in populations at very low risk for infections with *M. tuberculosis*. Problems with the specificity (a high percent of false-positive reactions) of a tuberculin skin test can result in mistaken diagnoses of infection in uninfected persons, and have the following potential adverse clinical and public health consequences: (1) inappropriate use of isoniazid preventive therapy, (2) unnecessary use of health care resources, (3) unnecessary contact investigations, and (4) interference with the acceptability of the tuberculin skin test by clinicians as a tool for diagnosing infection with *M. tuberculosis*.

It is well recognized that false-positive tuberculin skin test results may arise from a number of sources related to the person applying the test and to the person receiving the test. However, there have also been sufficient concerns about commercial skin test antigens themselves causing false-positive reactions to warrant further investigation. Information from our study will be used to evaluate whether current procedures used by PHS for standardizing tuberculin skin test antigens are adequate, and to resolve the question of whether the products are equivalent and can be used interchangeably or whether one of the products is more likely than the other to produce an excess of false-positive reactions.

The study will be conducted at six clinical sites located in the United States, each of which will recruit 250 patients. These sites were recruited through open competitions announced in 1996, and the protocol development and implementation are scheduled for 1997. The study sites and principal investigators are the Seattle-King County Health Department, Dr. Charles Nolan; Denver Health and Hospitals, Dr. William Burman; the University of Arizona, Dr. Linda Lundergan; the University of California at San Diego, Dr. Antonino Catanzaro; Emory University, Dr. Naomi Bock; and the Marion County Health Department, Dr. Crystal Jones. Michael J. Brennan, PhD, Chief, Laboratory of Mycobacteriology, Center for Biologics Evaluation and Research, Food and Drug Administration (FDA), will act as a technical consultant and as the mediator for the FDA.

If you have any questions about the clinical trial, please call the Research and Evaluation Branch, DTBE, at (404) 639-8123.

*—Reported by Elsa Villarino, MD, MPH
Division of TB Elimination*

INTERNATIONAL NOTES

Training Needs Assessment of Panel Physicians

US immigration law, which is established by Congress, mandates the overseas medical screening of immigrants and refugees. The general goal is to exclude (1) persons who have communicable diseases of public health significance or physical or mental disorders associated with harmful behavior, drug abuse, or addiction, or (2) persons who are likely to become a public charge. According to this law, details concerning the specific diseases to be excluded, the persons to be screened, and the

examination and studies to be performed are prescribed by the Public Health Service of the Department of Health and Human Services, with oversight provided by the Division of Quarantine (DQ) at CDC. The current list of infectious diseases of public health significance that warrant exclusion includes infectious TB, HIV infection, leprosy, and certain sexually transmitted diseases.

The overseas medical examination, which is valid for 12 months, is performed by panel physicians, who are local physicians appointed by the US consulate. In some cases, clinics or hospitals are designated as "panel physicians," as is the case in two of the highest-volume screening sites, Vietnam and the Philippines. Panel physicians are provided with a book of technical instructions concerning the examination process; this examination consists of a TB screening (i.e., a chest radiograph), as well as a history and physical examination and screening for physical and mental disorders, substance abuse, sexually transmitted diseases, leprosy, and HIV infection. There is no formal certification process. Each panel physician is expected to make local arrangements for the radiologic and laboratory examinations required as part of the evaluation. At present, none of the countries have on-site supervision beyond the local US consular official. Panel physicians do, however, receive periodic supervisory visits by two CDC staff members based in Frankfurt, Germany, and Bangkok, Thailand. The participating physicians are directly reimbursed by immigrant applicants using a fee scale set locally; in the case of refugees, the US government reimburses the panel physician for the screening services. There are approximately 800 panel physicians worldwide.

Because of increased attention and concern regarding the identification and treatment of TB

among immigrants and refugees entering the United States, and because of the lack of standards for and review of training and credentials of overseas panel physicians, CDC's Divisions of Quarantine and TB Elimination decided to conduct an assessment of the training needs and capacities of panel physicians. Consequently, in August 1996 CDC hired a contractor, Linda Potts, MBA, MPH, to design, conduct, and analyze a needs assessment for panel physicians. This assessment will

- Determine the current knowledge, skills, and abilities of panel physicians in regards to screening for TB
- Identify the training/education needs of panel physicians
- Identify the factors or incentives that motivate panel physicians to complete a training/certification program
- Determine the language/cultural differences that will require adjustments to a training/education program for panel physicians
- Identify the factors that cause difficulties in-country in maintaining compliance with US immigration law

Ms. Potts is responsible for developing and implementing a needs assessment tool to determine the panel physicians' training needs. Based on the findings, she will then recommend training to address these needs as well as identify factors that could positively motivate panel physicians to participate in the training.

This project will target panel physicians in the countries with the highest incidence of immigrants and refugees to the US with TB: Vietnam, the Philippines, Haiti, China, Mexico, and India (approximately 30 total physicians). Additionally, panel physicians in two yet-to-be-identified countries will be included in this project. It is

anticipated that the needs assessment will be completed by mid-1997.

—Reported by Nancy Binkin, MD, MPH
Division of TB Elimination

NEWS BRIEFS

The Research and Evaluation Branch of DTBE is planning a meeting for consultation on "Use of Skin Tests and Issues in Preventive Therapy for TB in HIV-Infected Persons." The meeting is planned for February 5 - 6, 1997. The attendees will be invited experts, and the results of the meeting discussions will be used in revisions of existing guidelines, including those for anergy testing.

§

Public health nurses in the New York City Bureau of TB Control have developed and published a document entitled *Nursing Diagnoses & Interventions in Tuberculosis Control*, which is designed to enhance the quality of care through improved communication among members of the multidisciplinary patient care team in TB control. These recommendations are formulated specifically to address barriers to treatment encountered in patients with TB. It was developed from the experience of public health nurses who have worked in TB control for more than a decade. To order, or for additional information, write to

Bureau of TB Control - Clinical Services
New York City Department of Health
225 Broadway, 22nd Floor, Box 72B
New York, NY 10007

TRAINING AND EDUCATIONAL MATERIALS

The Self-Study Modules on Tuberculosis course is available as a distance learning course from

CDC's Public Health Training Network. It consists of a set of five educational modules, an introduction, and a glossary designed to provide basic information about TB in a self-study format. The modules, which were developed by DTBE and the Division of Media and Training Services, PHPPPO, CDC, cover the following topics: "Transmission and Pathogenesis of TB," "Epidemiology of TB," "Diagnosis of TB Infection and Disease," "Treatment of TB Infection and Disease," and "Infectiousness and Infection Control." The target audience is entry-level TB workers and any staff of facilities serving persons with or at risk for TB. To enroll or for more information about this Distance Learning Course, contact CDC's Public Health Training Network Distance Learning Program at 1 (800) 41-TRAIN.

NEW PUBLICATIONS

Allos BM, Gensheimer KF, Bloch AB, et al. Management of an outbreak of tuberculosis in a small community. *Ann Intern Med* 1996; 125(2):114-7.

CDC. Characteristics of foreign-born Hispanic persons with tuberculosis—eight U.S. counties bordering Mexico, 1995. *MMWR* 1996; 45(47):1032-6.

CDC. Clinical update: impact of HIV protease inhibitors on the treatment of HIV-infected tuberculosis patients with rifampin. *MMWR* 1996;45(42):921-5.

CDC. Nucleic acid amplification tests for tuberculosis. *MMWR* 1996;45(43):950-2.

Carey JW, Morgan M, Oxtoby MJ. Intercoder agreement in analysis of responses to open-ended interview questions: examples from tuberculosis research. *Cultural Anthropology*

Methods Journal 1996;8(3):1-5.

Frieden TR, Sherman LF, Maw KL, et al. A multi-institutional outbreak of highly drug-resistant tuberculosis. *JAMA* 1996;276: 1229-35.

PERSONNEL NOTES

Michael Carson has been selected for a TB public health advisor position in the Florida Department of Health. Since January 1995, Mike has been assigned to the California Department of Health Services and has worked on location with the TB program staff of the Orange County Health Care Agency in Santa Ana. From February 1993 until his transfer to California, he was assigned to the Bureau of TB Control, New York City Department of Health. In Florida he will be an assistant to State officials and the senior public health advisor and, among other duties, will be responsible for coordinating TB program operations in a designated region. Mike will transfer from Santa Ana to Tallahassee on January 19, 1997.

Bill Coggin, DTBE's public health advisor assigned to the TB program of the Baltimore City Health Department, was selected for a temporary duty assignment in Rwanda, Africa, beginning on November 27 and ending on or about December 18, 1996. The assignment was in response to a request from the American Red Cross (ARC) for a French-speaking public health advisor to travel to Rwanda for a 2- to 3-week health assessment mission under the auspices of the International Federation of the Red Cross and Red Crescent Societies (IFRC). The scope of work for this mission is to assess the long-term health issues associated with the massive refugee movement from eastern Zaire to Rwanda. The anticipated date of Bill's return to duty in Baltimore is December 23.

Paula Fujiwara, MD, has been selected for the position of the Director of the Bureau of TB Control in the New York City Department of Health to replace Dr. Tom Frieden, who recently left for a detail to the World Health Organization in New Delhi, India. Dr. Fujiwara has 8 years of TB experience, both in the San Francisco TB program and the New York City TB program. She has played a very significant role in the recent successes in the NYC TB program with significant decreases in cases and drug resistance. She is regarded as a national and international expert in both the clinical and public health aspects of TB prevention and control, and has a keen understanding of the challenges facing TB prevention and control in New York City, nationally and internationally.

Scott Jones has been selected for the vacant TB public health advisor position in the Louisiana Department of Health and Hospitals. He has been assigned to the TB program of the City of New Orleans since May 1996. He relocated from the New Orleans Wetmore TB Clinic to the State health department, which is in New Orleans, on November 10, 1996.

Jim McAuley, MD, has been selected for the CDC medical officer position in the Chicago TB control program. He will be responsible for various activities related to program evaluation and policy development. He will be working to continue and augment the program's recent successes in improving completion of therapy in their clinics and develop and implement systems to improve completion rates in the private sector and at Cook County Hospital.

Rose Pray has been selected for the position of Training Specialist in the Communications and Education Branch of DTBE. In this position, Rose will serve as the focal point, technical expert, and

administrative manager for all training and curriculum development activities and materials in the Division. After earning a Master of Science degree in Nursing from the UC at San Francisco in 1979, Rose spent the next 11 years in Alaska working as a Public Health Nurse, a Nursing Instructor at the University of Alaska, and the Nurse Consultant with the Health Department's TB Program. From 1991 to 1994, Rose worked as a Program Consultant with the World Health Organization where she developed a curriculum and provided training as part of a tuberculin survey in Nicaragua, developed a TB program review manual for the WHO TB program, and participated in a comprehensive TB program review for India. From 1994 to 1996, as a Technical Officer with WHO, she collaborated with Ministries of Health, faculty of training institutions, and pertinent program staff of various countries in the development, implementation, and evaluation of training curricula. Rose started work on November 25.

Paul Tribble, DTBE's public health advisor assigned to the Arizona Department of Health Services, has accepted a position with the Division of Quarantine, National Center for Infectious Diseases. He transferred to his new job with the Division of Quarantine in Atlanta on December 8, 1996. We would also like to congratulate Paul for the 1996 Director's Special Merit Team Award that was presented to him and other members of the TB Elimination Section of the Arizona Department of Health. The award was presented by the Arizona Department of Health Services for the group's contributions last March in managing a person with MDR TB at a corrections facility in Florence, Arizona.

CALENDAR OF EVENTS

January 9-10, 1997

**TB Case Management for Nurses
Newark, New Jersey**

Debra Bottinick
NJ Medical School National TB Center
(201) 982-3270

January 14-16, 1997

**Effective TB Interviews, Part II: Targeting
Special Populations
Martinez, California**

National Training Coordinator
Francis J. Curry National TB Center
(415) 502-4600

January 15, 1997

**TB Update for Clinicians
Lodi, California**

Statewide Training Coordinator
Francis J. Curry National TB Center
(415) 502-4600

January 23 and 30 and February 6, 1997

**Tuberculosis 2000: Fundamentals of Clinical
TB and TB Control
San Francisco, California**

A joint project of the Francis J. Curry Natl. TB Center, the Charles P. Felton Natl. TB Center, and the NJ Medical School Natl. TB Center, this is a 3-part live, interactive satellite course for medical professionals. It will be broadcast to hundreds of satellite downlink sites throughout the US. Broadcast times: 1 - 3 pm, Eastern time; noon - 2 pm, Central time; 11 am - 1 pm, Mountain time; 10 am - noon, Pacific time. To register your site to receive the broadcast or to learn about the nearest broadcast viewing site, contact the TB 2000 office:
Francis J. Curry National TB Center
Fax: (415) 502-7561

E-mail: tb2000@nationaltbcenter.edu

February 7, 1997

**Mantoux Tuberculin Skin Test Course
Newark, New Jersey**

Debra Bottinick
NJ Medical School National TB Center
(201) 982-3270

February 10-14 and April 14-18, 1997

**Postgraduate Course on Clinical Management
and Control of TB
Denver, Colorado**

Catheryne J. Queen
National Jewish Center for Immunology and
Respiratory Medicine
(303) 398-1700

February 12-14, 1997

**TB Intensive
San Francisco, California**

National Training Coordinator
Francis J. Curry National TB Center
(415) 502-4600

February 24, 1997

**TB Update I - Medical Management of TB
Newark, New Jersey**

Debra Bottinick
NJ Medical School National TB Center
(201) 982-3270

February 27-March 2, 1997

**2nd Annual Meeting of the IUATLD, North
American Region
"The Role of the Public and Private Sectors in
Global TB Control"
Chicago, Illinois**

Intl. Union Against TB and Lung Disease
Allan Shaw
Tel: (312) 243-2003/Fax: (312) 243-3954

March 18-20, 1997

**Case Management & Contact Investigation
Anchorage, Alaska**

National Training Coordinator
Francis J. Curry National TB Center
(415) 502-4600

March 19-21, 1997

**TB Program Manager's Course
Newark, New Jersey**

Debra Bottinick
NJ Medical School National TB Center
(201) 982-3270

March 20-23, 1997

**Prevention 97: Science, Technology, and
Practice
Atlanta, Georgia**

Will address the latest advances in the field of
preventive medicine
American College of Preventive Med. &
Assoc. of Teachers of Preventive Med.
Tel: (202) 466-2569/Fax: (202) 466-2662

April 11, 1997

**Preventing TB in the Workplace
Newark, New Jersey**

Debra Bottinick
NJ Medical School National TB Center
(201) 982-3270

April 17-18, 1997

**Fourth Northeast TB Controllers Conference
North Falmouth, Massachusetts**

Massachusetts DPH, Division of TB Prevention &
Control
A conference for TB controllers in Public Health
Service regions I, II, and III
Kathy Hursen
Tel: (617) 983-6970/Fax: (617) 983-6990

Recommendations for Counting Reported Tuberculosis Cases (Draft) December 1996

Since publication of the "Recommendations for Counting Reported Tuberculosis Cases"¹ in January 1977, numerous changes have occurred and many issues have been raised within the field of tuberculosis (TB) surveillance. This current version updates and supersedes the previous version; it clarifies the parameters for counting TB cases among (a) immigrants, resident aliens, and border crossers, (b) military personnel stationed in the United States and abroad, and (c) persons diagnosed within the Indian Health Service and correctional facilities.

A distinction should be made between **reporting** TB cases to a health department and **counting** TB cases for determining incidence of disease. Throughout each year, TB cases and suspected cases are reported to public health authorities by sources such as clinics, hospitals, laboratories, and health care providers. From these reports, the state or local TB control officer must determine which cases meet the current surveillance definition for TB disease. These verified TB cases are then counted and reported to CDC.

I. Reporting TB Cases.—CDC recommends that health care providers and laboratories be required to report all TB cases or suspected cases to state and local health departments based on the current "Case Definition for Public Health Surveillance."² This notification is essential in order for TB programs to

- Ensure case supervision
- Ensure completion of appropriate therapy
- Ensure completion of timely contact investigations
- Evaluate program effectiveness
- Assess trends and characteristics of TB morbidity

II. TB Surveillance.—For purposes of surveillance, a case of TB is defined on the basis of laboratory and/or clinical evidence of active disease due to *M. tuberculosis* complex.*

****Mycobacterium tuberculosis* complex** (*M. tuberculosis* complex) consists of three mycobacterial species: *M. tuberculosis*, *M. bovis*, and *M. africanum*. These species are identical in DNA homology studies. In terms of their ability to cause clinical disease and be transmissible from person to person, *M. bovis* and *M. africanum* behave like *M. tuberculosis*; therefore, disease caused by any of the three organisms should be reported as TB, using the Report of Verified Case of Tuberculosis (RVCT). The only exception is the BCG strain of *M. bovis*, which may be isolated from persons who have received the vaccine for protection against TB or as cancer immunotherapy; disease caused by this *M. bovis* strain should not be reported as TB because the transmission is iatrogenic (treatment-induced), rather than person-to-person or communicable.

a. Laboratory Case Definition.

- Isolation of *M. tuberculosis* complex from a clinical specimen. The use of rapid-identification techniques for *M. tuberculosis* performed on a culture from a clinical specimen, such as DNA probes and high-pressure liquid chromatography (HPLC), is acceptable under this criterion.

OR

- Demonstration of *M. tuberculosis* from a clinical specimen by nucleic acid amplification (NAA) test. NAA tests must be accompanied by cultures of mycobacterial species. However, for surveillance purposes, CDC will accept results obtained from NAA tests that are approved by the Food and Drug Administration (FDA) and used according to the approved product labeling on the package insert. Current FDA-approved NAA tests are only approved for use on smear-positive respiratory specimens.

OR

- Demonstration of acid-fast bacilli (AFB) in a clinical specimen when a culture has not been or cannot be obtained; historically this criterion has been most commonly used to diagnose TB in the postmortem setting.

b. Clinical Case Definition.—In the absence of laboratory confirmation of *M. tuberculosis* complex after a diagnostic process has been completed, persons must have **all** of the following criteria for clinical TB:

- Evidence of TB infection based on a positive tuberculin skin test

AND

- One of the following:
 - (1) Signs and symptoms compatible with current TB disease, such as an abnormal or unstable (worsening or improving) chest radiograph, or
 - (2) Clinical evidence of current disease (e.g., fever, night sweats, cough, weight loss, hemoptysis)

AND

- Current treatment with two or more anti-TB medications

NOTE: The case definition described herein was developed for use in this document and is not intended to replace the case definition for TB as stated in the current “Case Definition for Public Health Surveillance.”

In addition, the software for TB surveillance developed by CDC includes a calculated variable called “Vercrit,” for which one of the values is “Provider Diagnosis.” “Provider Diagnosis” is selected when the

user chooses to override a "Suspect" default value in the case verification screen as "Verified by Provider Diagnosis." Thus, "Provider Diagnosis" is not a component of the case definition for TB in the current "Case Definition for Public Health Surveillance" publication. CDC's national morbidity reports have traditionally included all cases that are considered verified by the reporting areas, without a requirement that cases meet the published case definition.

III. Counting TB Cases.—Cases that meet the current CDC surveillance case definition for verified TB are counted by 56 reporting areas with count authority (i.e., the 50 state health departments, the District of Columbia, New York City, Puerto Rico, Guam, the Republic of Palau, and the U.S. Virgin Islands) to determine annual incidence. Laboratory and clinical case definitions are the two primary diagnostic categories used by the CDC "Case Definition for Public Health Surveillance."

Most verified TB cases are accepted for counting based on laboratory confirmation of *M. tuberculosis* complex from a clinical specimen.

A person may have more than one discrete (separate and distinct) episode of TB. If disease recurs in a person within any 12-consecutive-month period, count only one episode as a case for that year. However, if TB disease recurs in a person, **and** if more than 12 months have elapsed since the person was discharged from or lost to supervision, the TB is considered a separate episode and should be counted as a new case.

Mycobacterial diseases other than those caused by *M. tuberculosis* complex should not be counted in TB morbidity statistics unless there is concurrent TB.

a. Verified TB Cases.

COUNT

Count only verified TB cases that meet the laboratory or clinical case definitions (see Section II). The diagnosis of TB must be verified by the TB control officer or designee. The current CDC surveillance case definition for TB describes and defines the criteria to be used in the case definition for TB disease.

DO NOT COUNT

If diagnostic procedures have not been completed, do not count; wait for confirmation of disease. Do not count a case for which two or more anti-TB medications have been prescribed for preventive therapy for exposure to multidrug-resistant (MDR) TB, or while the diagnosis is still pending.

b. Nontuberculous Mycobacterial Diseases (NTM).

COUNT

An episode of TB disease diagnosed concurrently with another nontuberculous mycobacterial disease should be counted as a TB case.

DO NOT COUNT

Disease attributed to or caused by nontuberculous mycobacteria alone should not be counted as a TB case.

c. TB Cases Reported at Death.**COUNT**

TB cases first reported to the health department at the time of a person's death are counted as incident cases provided that the person had current disease at the time of death. The TB control officer should verify the diagnosis of TB.

DO NOT COUNT

Do not count as a case of TB if there is no evidence of current disease at the time of death or at autopsy.

d. Immigrants, Refugees, Permanent Resident Aliens, Border Crossers,* and Foreign Visitors.⁴**COUNT**

Immigrants and refugees who have been screened overseas for TB and

- have been classified as Class B (B1, B2, or B3)³ or resident aliens
- are not already on anti-TB medications for treatment of tuberculous disease, and
- are examined after arriving in the United States and diagnosed with clinically active TB requiring anti-TB medications

should be counted by the locality of their current residence at the time of diagnosis regardless of citizenship status.

Border crossers* and permanent resident aliens who are diagnosed with TB and plan to receive anti-TB therapy from a locality in the United States for 90 days or more should be counted by the locality where they receive anti-TB therapy.

Foreign visitors (e.g., students, commercial representatives, and diplomatic personnel) who are diagnosed with TB, are receiving anti-TB therapy, **and** plan to remain in the United States for 90 days or more should be counted by the locality of current residence.

*Border crosser - defined, in part, by the Immigration and Naturalization Service (INS)⁴ as "a nonresident alien entering the United States across the Mexican border for stays of no more than 72 hours." Border crossers may go back and forth across the border many times in a short period.

DO NOT COUNT

TB cases in immigrants or refugees who have been classified as Class A with a waiver (TB, infectious, "Noncommunicable for travel purposes")³ should not be counted as new cases even if the persons receive routine initial work-ups in the United States.

TB in persons who are temporarily (<90 days) in the United States, for whom therapy may have been started but who plan to return to their native country to continue therapy, should not be counted in the United States.

e. Out-of-State or Out-of-Area Residents.

COUNT

A person's TB case should be counted by the locality in which he or she resides at the time of diagnosis. TB in a person who has no address should be counted by the locality that diagnosed and is treating the TB. The TB control officer should notify the appropriate out-of-state or out-of-area TB control officer of the person's home locality to (1) determine whether the case has already been counted to avoid "double counting," and (2) agree on which TB control office should count the case if it has not yet been counted.

DO NOT COUNT

Do not count a case in a newly diagnosed TB patient who is an out-of-area resident and whose TB has already been counted by the out-of-area TB control office.

f. Migrants and Other Transients.

COUNT

Persons without any fixed U.S. residence are considered to be the public health responsibility of their present locality and their TB case should be reported and counted where diagnosed.

DO NOT COUNT

Cases in transient TB patients should not be counted when there is evidence that they have already been counted by another locality.

g. Federal Facilities (e.g., Military and Veterans Administration Facilities).

COUNT

Cases in military personnel, dependents, or veterans should be reported and counted by the locality where the persons are residing in the United States at the time of diagnosis and initiation of treatment.

However, if military personnel or dependents are discovered to have TB at a military base outside the United States but are referred elsewhere for treatment (e.g., a military base located within the United States), the TB case should be reported and counted where treated and not where the diagnosis was made.

DO NOT COUNT

Do not count if the case was already counted by another locality in the United States.

h. Indian Health Service.

COUNT

TB should be reported to the local health authority (e.g., state or county) and counted where diagnosed and treatment initiated. However, for a specific group such as the Navajo Nation, which is geographically located in multiple states, health departments should discuss each case and determine which locality should count the case.

DO NOT COUNT

Do not count if the case was already counted by another locality.

i. Correctional Facilities (e.g., Local, State, Federal, and Military).

COUNT

Persons who reside in local, state, federal, or military correctional facilities may frequently be transferred or relocated within and/or between various correctional facilities. TB in these persons should be reported to the local health authority and counted by the locality where the diagnosis was made and treatment plans were initiated.

DO NOT COUNT

Do not count correctional facility residents' TB cases that were counted elsewhere by another locality or correctional facility, even if treatment continues at another locale or correctional facility.

j. Peace Corps, Missionaries, and Other Citizens Residing Outside the United States.

DO NOT COUNT

TB in persons diagnosed outside the United States should not be counted. TB in these persons should be counted by the country in which they are residing regardless of their plans to return to the United States for further work-up or treatment.

IV. Suggested Administrative Practices.—To promote uniformity in TB case counting, the following administrative procedures are recommended:

(a) All TB cases verified during the calendar year by a reporting area with count authority (e.g., state health department) by December 31 will be included in the incidence count for that year. Cases for which bacteriologic results are pending or for which confirmation of disease is questionable for any other reason should not be counted until their status is clearly determined; they should be counted at the time they meet the criteria for counting. This means that a case reported in one calendar year could be included in the morbidity count for the following year. The reporting area with count authority should ensure that there is agreement between final local and state TB figures reported to CDC.

Currently, some reporting areas may not use this suggested protocol. Some of these areas may wait until the beginning of the following year when they have received and processed all of the TB cases for inclusion in the annual case count for the previous year. If reporting areas decide to revise their

protocols, they should be aware that TB trends may change.

(b) TB is occasionally reported to health departments over the telephone, by letter or fax, or on forms other than the Report of Verified Case of Tuberculosis (RVCT). Such information should be accepted as an official morbidity report if sufficient details are provided; otherwise, the notification should be used as an indicator of a possible TB case (suspect) which should be investigated promptly for confirmation.

V. TB Surveillance Definitions.

Case - an episode of TB disease in a person meeting the laboratory or clinical criteria for TB as defined in the document "Case Definition for Public Health Surveillance"² (see Section II for criteria).

Suspect - a person for whom there is a high index of suspicion for active TB (e.g., a known contact to an active TB case or a person with signs/symptoms consistent with TB) who is currently under evaluation for TB disease.

Verification of a TB case - the process whereby a TB case, after the diagnostic evaluation is complete, is reviewed at the local level (e.g., state or county) by a TB control official who is familiar with TB surveillance definitions; if all the criteria for a TB case are met, the TB case is then verified and eligible for counting.

Counting of a TB case - the process whereby a reporting area with count authority evaluates verified TB cases (e.g., assesses for case duplication). These cases are then counted for morbidity in that locality (e.g., state or county) and reported to CDC for national morbidity counting.

***Mycobacterium tuberculosis* complex** (*M. tuberculosis* complex) - consists of three mycobacterial species: *M. tuberculosis*, *M. bovis*, and *M. africanum*. These species are identical in DNA homology studies. In terms of their ability to cause clinical disease and to be transmissible from person to person, *M. bovis* and *M. africanum* behave like *M. tuberculosis*; therefore, disease caused by any of the three organisms should be reported as TB, using the Report of Verified Case of Tuberculosis (RVCT). The only exception is the BCG strain of *M. bovis*, which may be isolated from persons who have received the vaccine to protect against TB or as cancer immunotherapy; disease caused by this *M. bovis* strain should not be reported as TB because the transmission is iatrogenic (treatment-induced), rather than person-to-person or communicable.

Nontuberculous mycobacteria (NTM) - mycobacteria other than *Mycobacterium tuberculosis* complex that can cause human infection or disease. Common nontuberculous mycobacteria include *M. avium* complex or MAC (*M. avium*, *M. intracellulare*), *M. kansasii*, *M. marinum*, *M. scrofulaceum*, *M. chelonae*, *M. fortuitum*, and *M. simiae*. Other terms have been used to represent NTM, including MOTT (mycobacteria other than TB) and "atypical" mycobacteria.

Reporting area - areas responsible for counting and reporting verified TB cases to CDC. Currently there are 56 reporting areas: the 50 states, the District of Columbia, New York City, Puerto Rico, Guam,

the Republic of Palau, and the U.S. Virgin Islands.

Alien - defined by the Immigration and Naturalization Service (INS)⁴ as “any person not a citizen or national of the United States.”

Border crosser - defined, in part, by the Immigration and Naturalization Service (INS)⁴ as “a nonresident alien entering the United States across the Mexican border for stays of no more than 72 hours.” Border crossers may go back and forth across the border many times in a short period.

Class A (TB, Infectious) - defined by the Division of Quarantine³ as an alien “with an abnormal chest radiograph or series of chest radiographs suggestive of current pulmonary TB and one or more positive sputum smear examinations for acid-fast bacilli.” This person is not authorized to enter the United States unless a waiver has been granted (see definition for Class A - TB, Infectious, “Noncommunicable for travel purposes.”)

Class A (TB, Infectious, “Noncommunicable for travel purposes”) - defined by the Division of Quarantine³ as an alien “with an abnormal chest radiograph or series of chest radiographs suggestive of active TB, a history of one or more positive sputum smear examinations for acid-fast bacilli, currently on recommended treatment, and sputum smears that are negative for acid-fast bacilli on 3 consecutive days.” This person is authorized to enter the United States if a waiver has been granted.

Class B1 (TB, clinically active, not infectious) - defined by the Division of Quarantine³ as an alien “with an abnormal chest radiograph or series of chest radiographs suggestive of active TB, and sputum smears that are negative for acid-fast bacilli on 3 consecutive days.” This person may be on anti-TB medications when entering the United States.

Class B1 (Extrapulmonary TB, clinically active, not infectious) - defined by the Division of Quarantine³ as an alien “with radiographic or other evidence of extrapulmonary TB, clinically active.” This person may be on anti-TB medications when entering the United States.

Class B2 (TB, not clinically active) - defined by the Division of Quarantine³ as an alien “with an abnormal chest radiograph or series of chest radiographs suggestive of active TB, not clinically active (e.g., fibrosis, scarring, pleural thickening, diaphragmatic tenting, blunting of costophrenic angles.) Sputum smears are not required.” Such a person who “completed the recommended course of anti-TB therapy and whose chest radiographs are stable should be reported as Class B2 - TB, treatment completed.” This person may be on anti-TB medications when entering the United States.

Class B3 (Consistent with TB, old or healed) - defined by the Division of Quarantine³ as an alien “with an abnormal chest radiograph or series of chest radiographs (the only abnormality is a calcified lymph node, calcified primary complex, or calcified granuloma). Sputum smears are not required.”

Immigrant - defined by the Immigration and Naturalization Service (INS)⁴ as “an alien admitted to the United States as a lawful permanent resident. Immigrants are those persons lawfully accorded the

privilege of residing permanently in the United States. They may be issued immigrant visas by the Department of State overseas or adjusted to permanent resident status by the Immigration and Naturalization Service of the United States."

Permanent Resident Alien - see Immigrant.

References

1. *Recommendations for Counting Reported TB Cases*. Atlanta: CDC, January 1977.
2. CDC. Case definition for public health surveillance. *MMWR* 1997; in press.
3. *Technical Instructions for Medical Examination of Aliens*. Atlanta: CDC, Division of Quarantine, revised July 13, 1992.
4. *Statistical Yearbook of the Immigration and Naturalization Service, 1994*. Washington, DC: US Department of Justice, Immigration and Naturalization Service, 1995.